US 20050187482A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0187482 A1**

O'Brien et al. (43) **Pub. Date: Aug. 25, 2005**

(54) **IMPLANTABLE WIRELESS SENSOR**

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(21) Appl. No.: **10/943,772**

(22) Filed: **Sep. 16, 2004**

Related U.S. Application Data

(60) Provisional application No. 60/503,745, filed on Sep. 16, 2003.

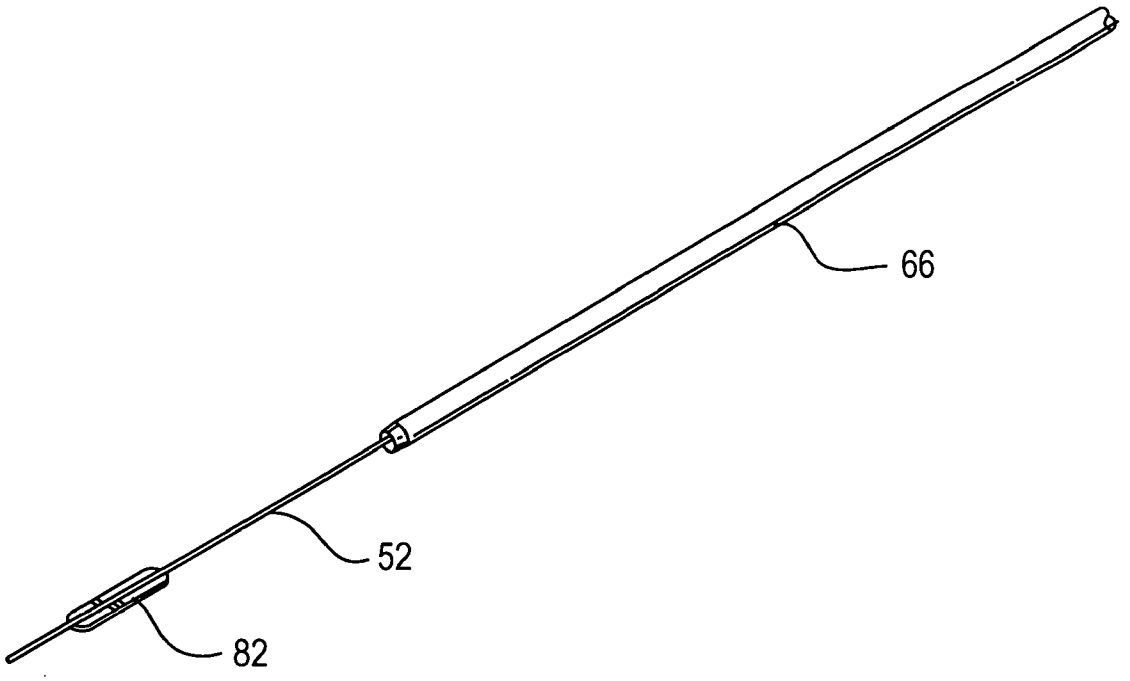
Publication Classification

(51) **Int. Cl.**[7] **A61B 5/00**; A61B 5/02

(52) **U.S. Cl.** **600/486**; 600/561; 128/903

(57) **ABSTRACT**

The progress of a endovascular aneurysm repair can be monitored by inserting a pressure transducer sensor using a catheter into the sac during endovascular aneurysm repair and then using a small, hand-held read out device to measure pressure easily, safely, inexpensively and accurately. In one aspect a sensor is introduced into the body by the steps of loading the sensor into a catheter, and deploying into the aneurysm sac. This invention also has other applications for measuring physical properties in patients or in other sites.



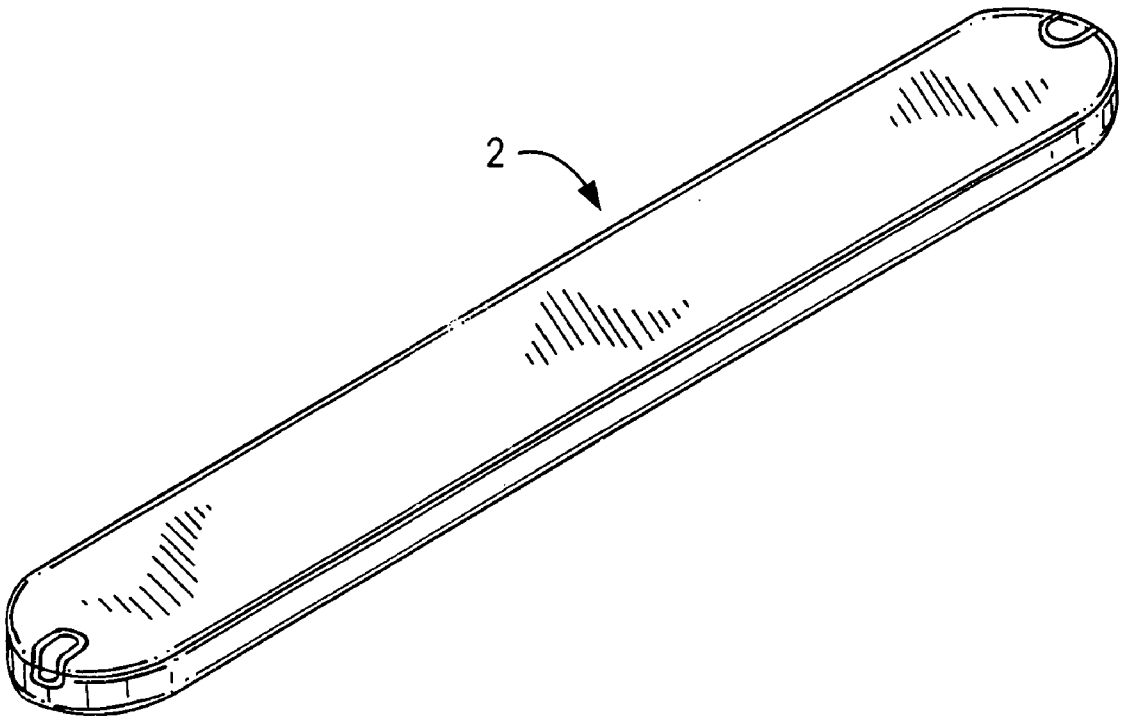


FIG. 1

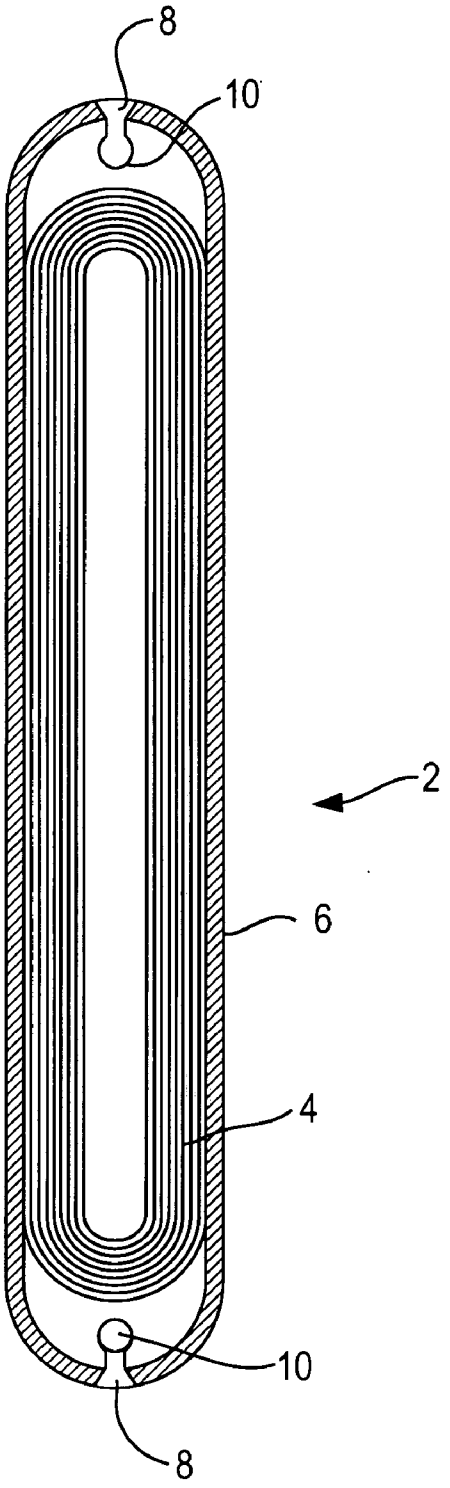


FIG. 2

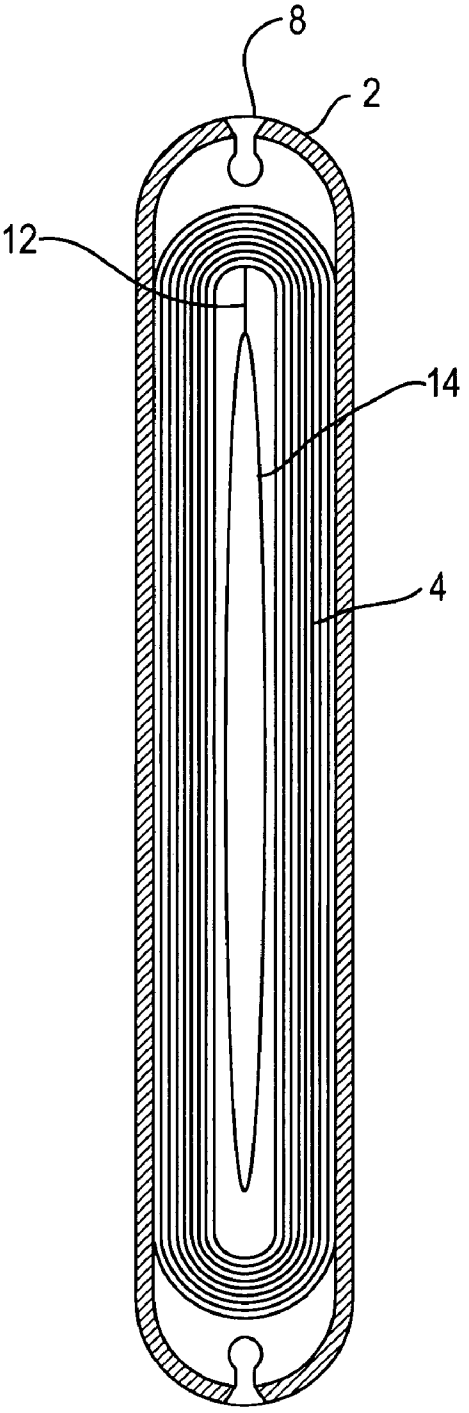


FIG. 3

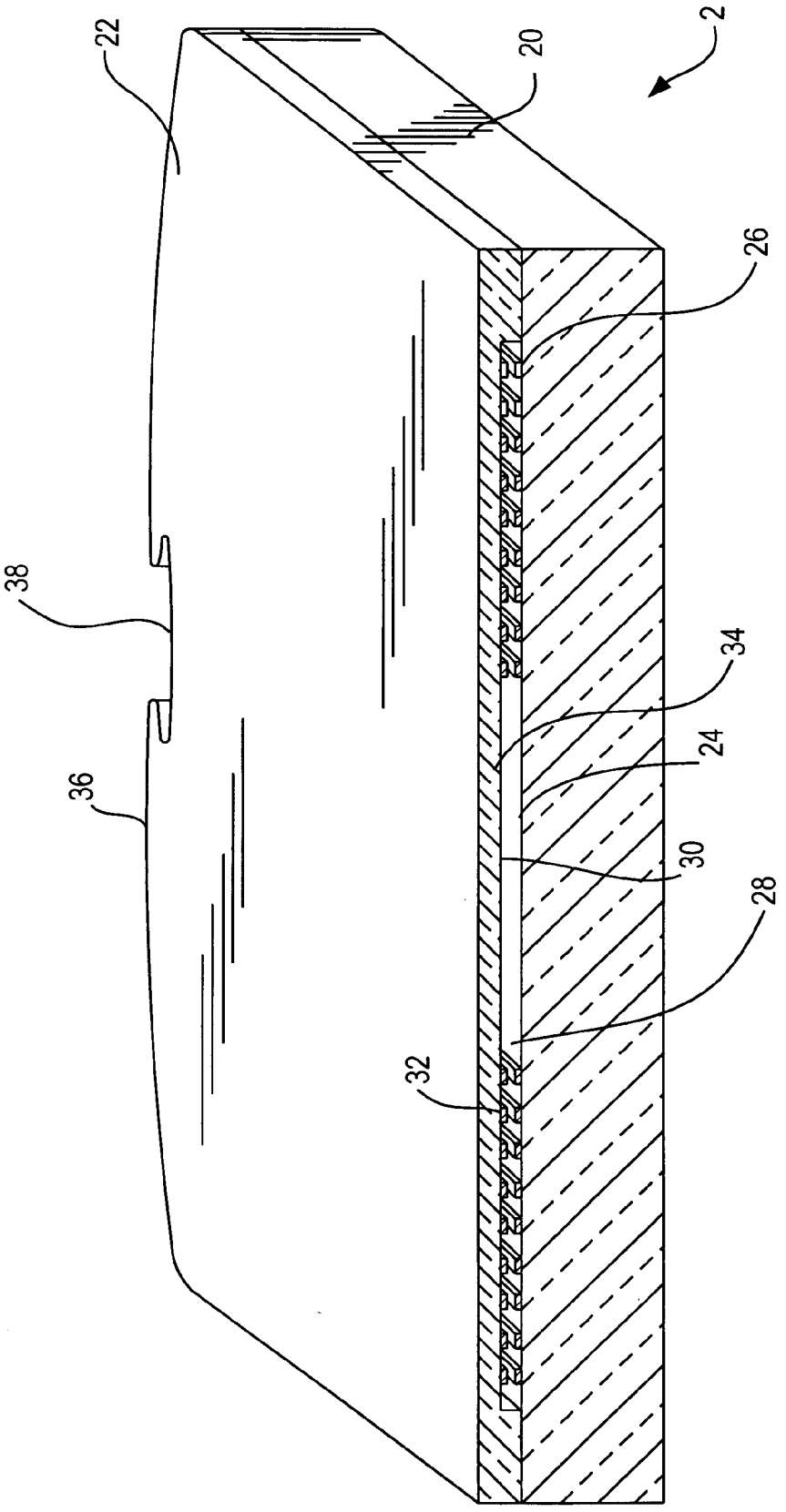


FIG. 4

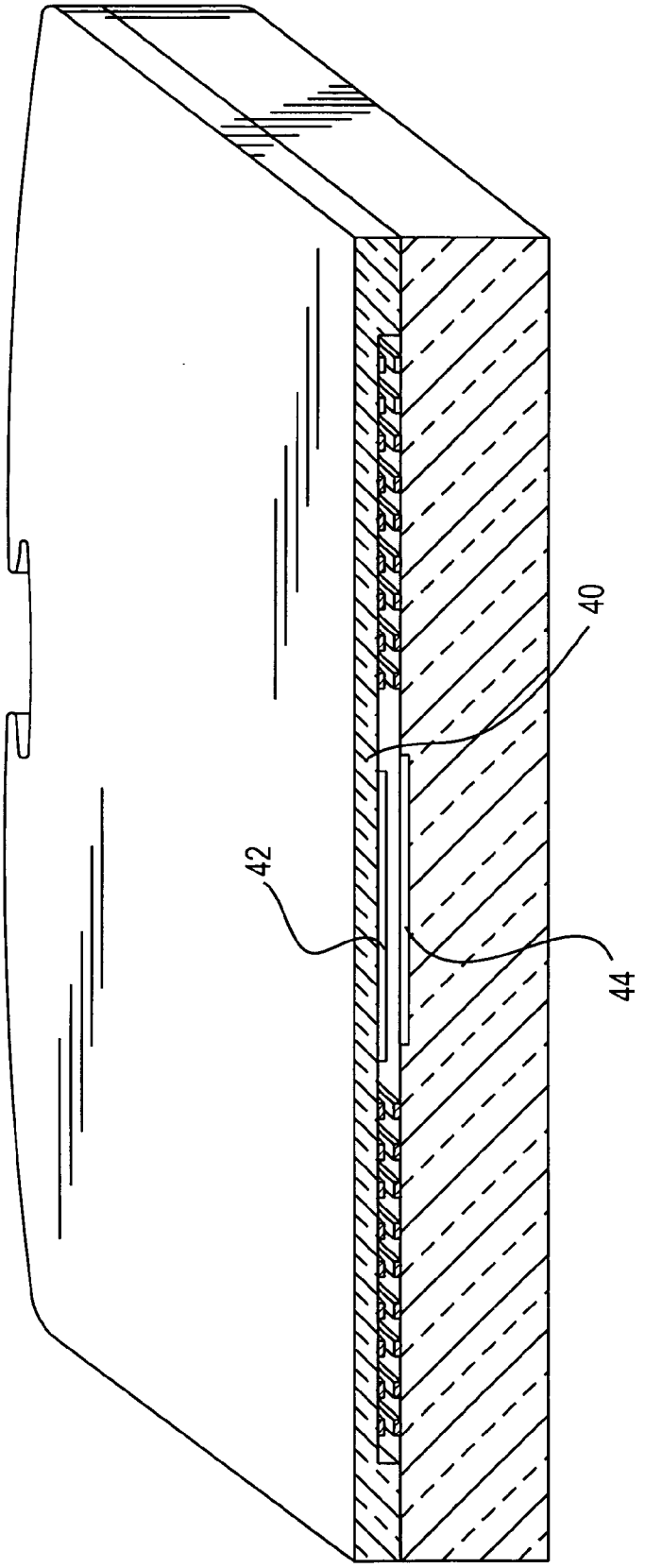


FIG. 5

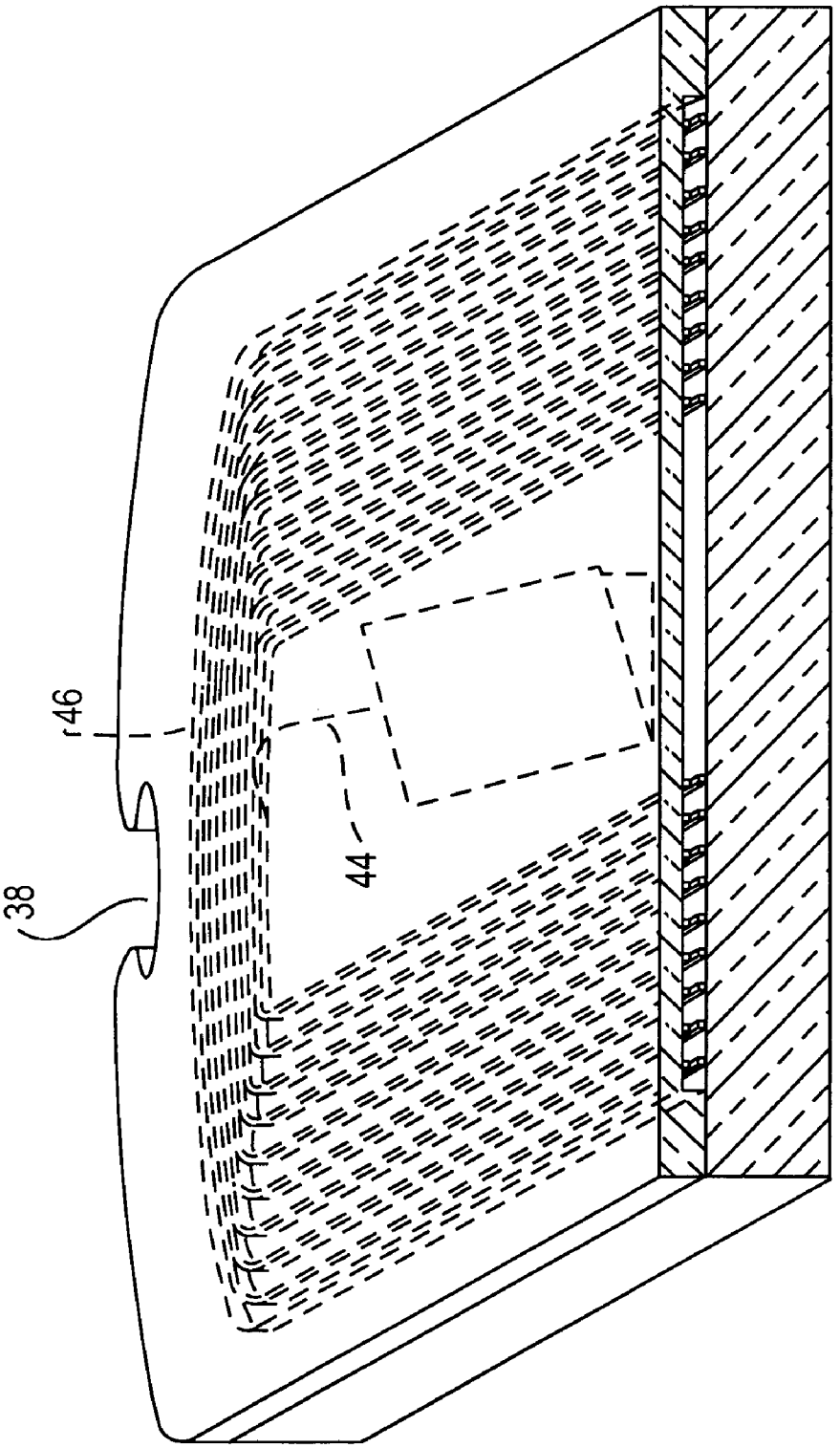


FIG. 6

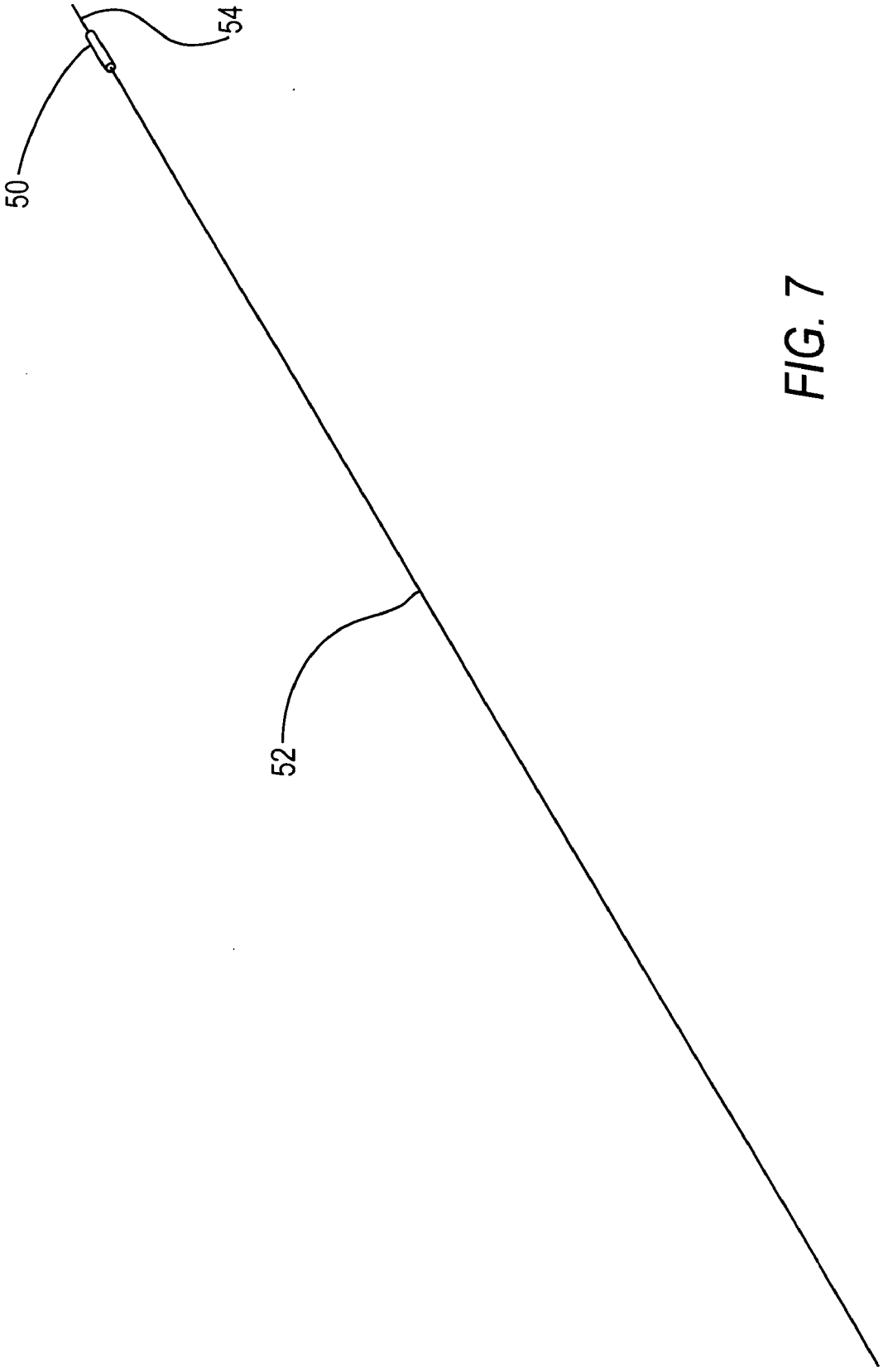


FIG. 7

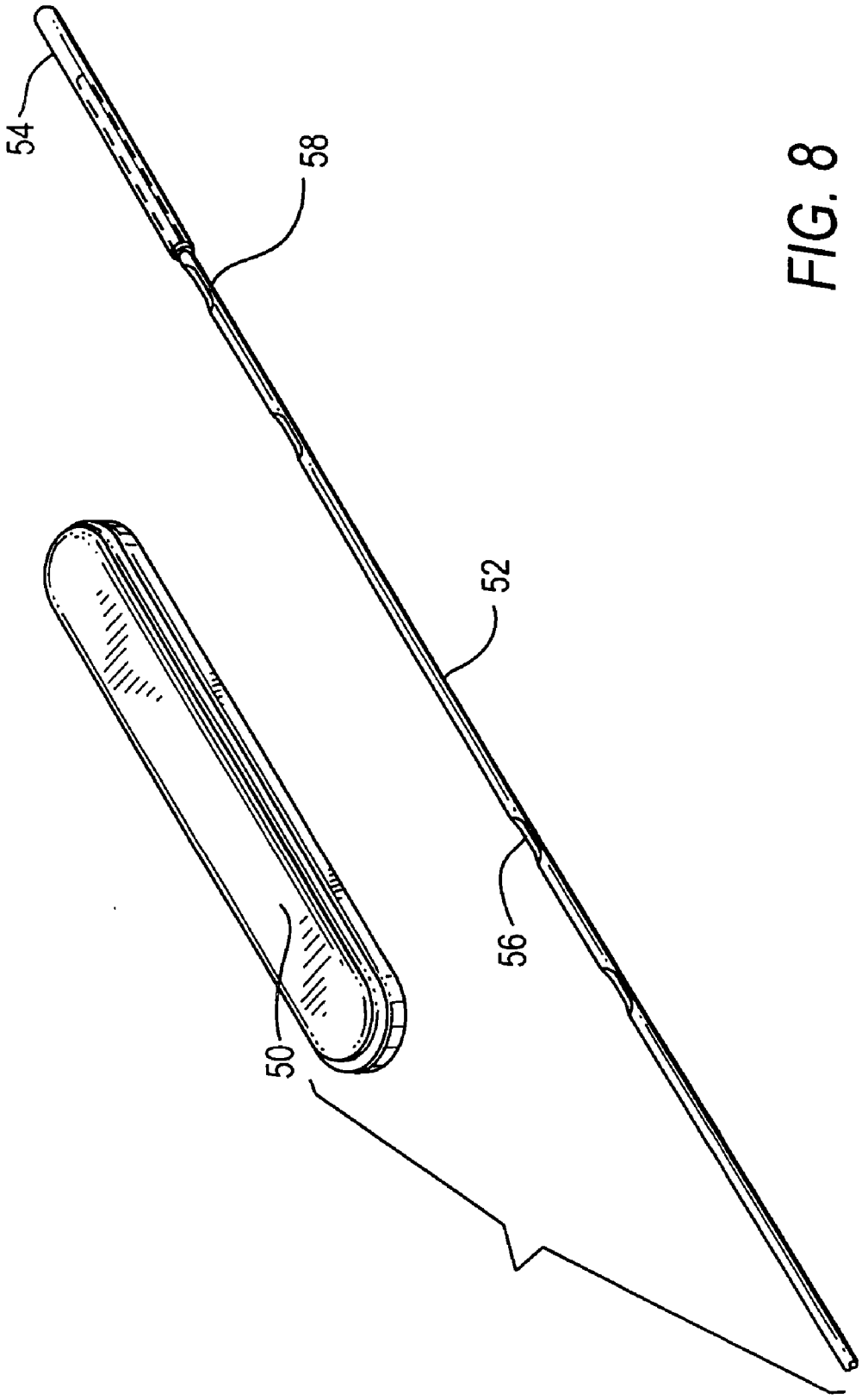


FIG. 8

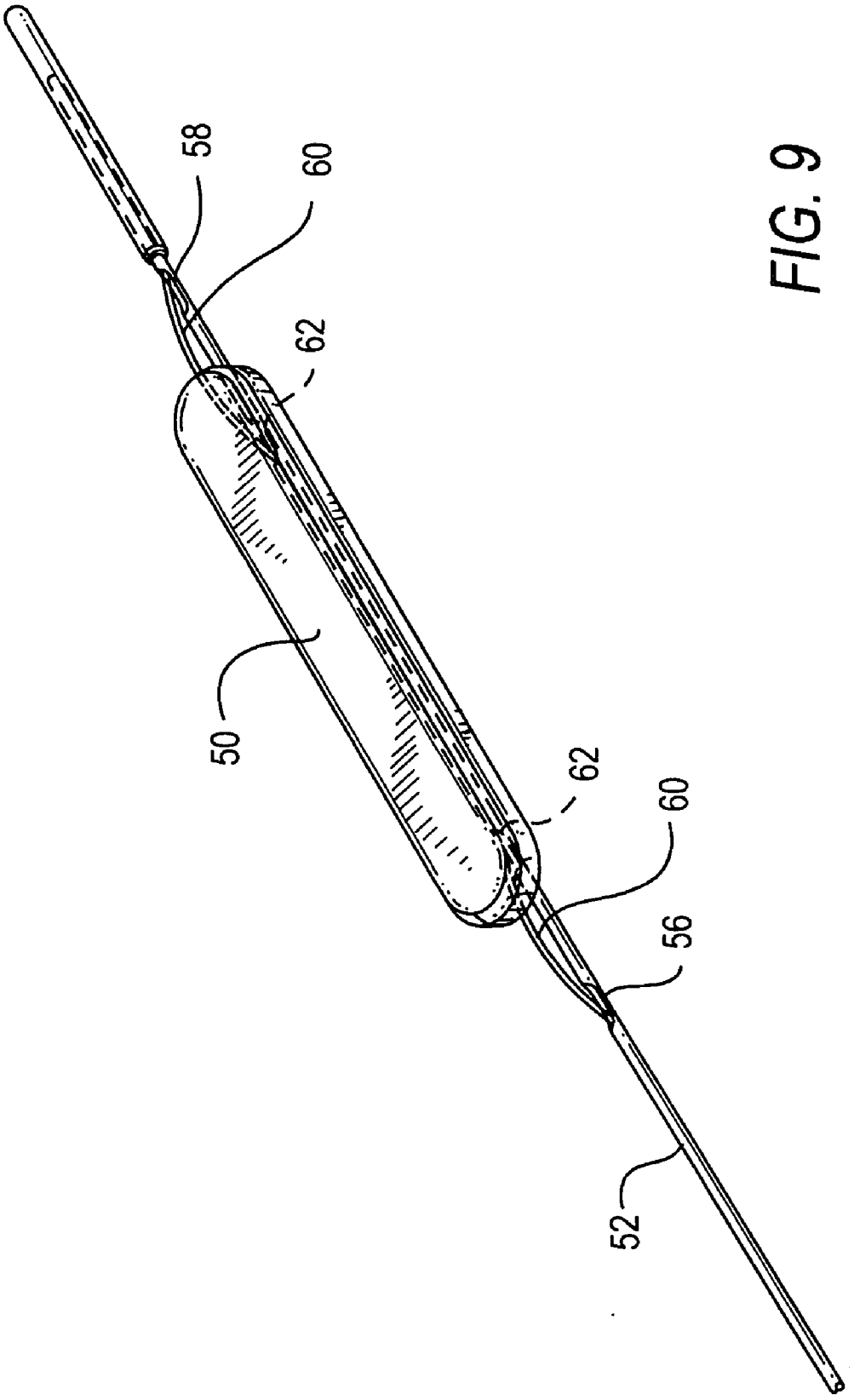


FIG. 9

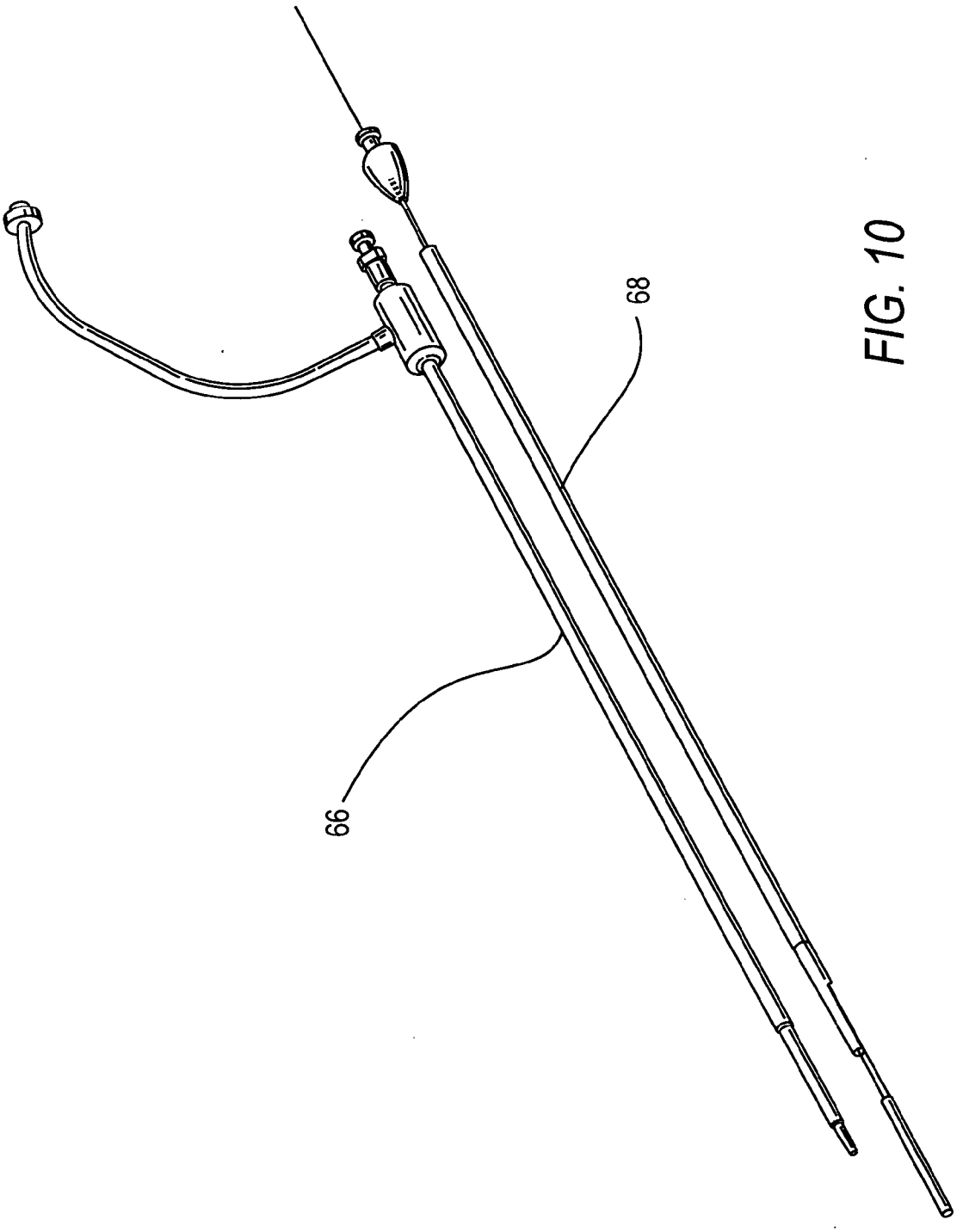


FIG. 10

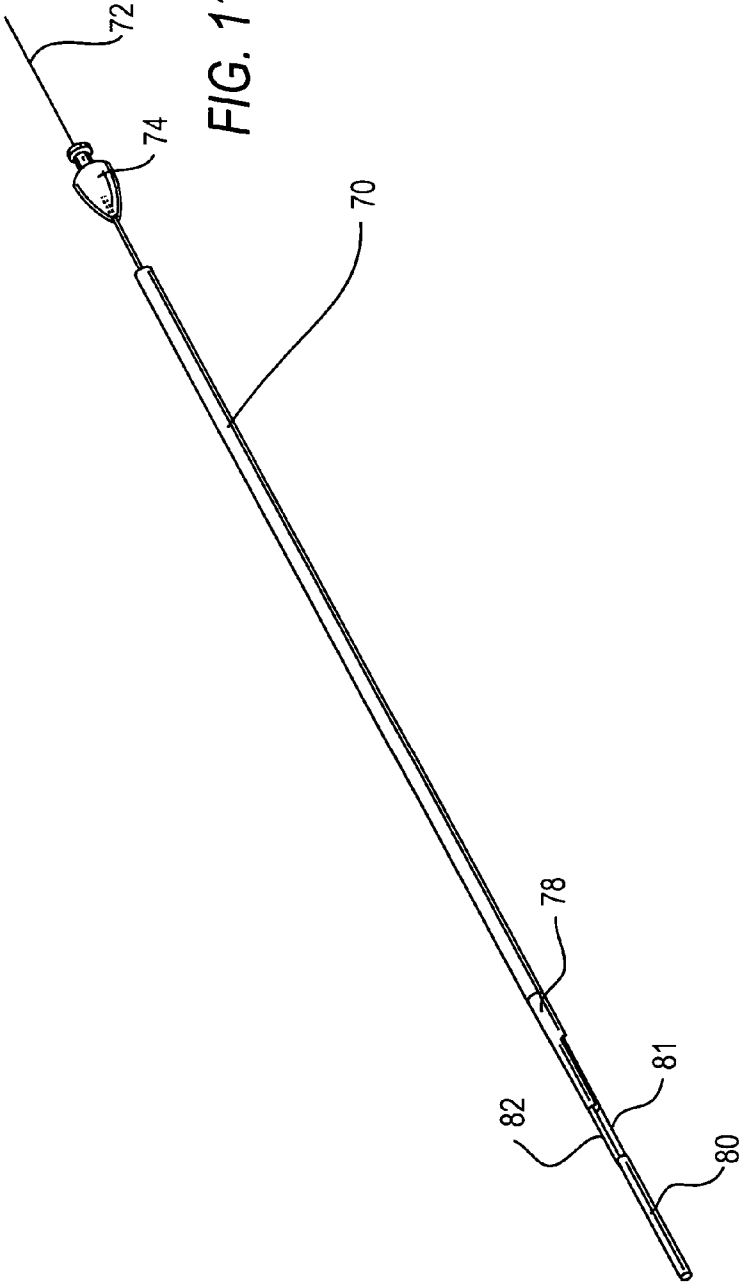


FIG. 11

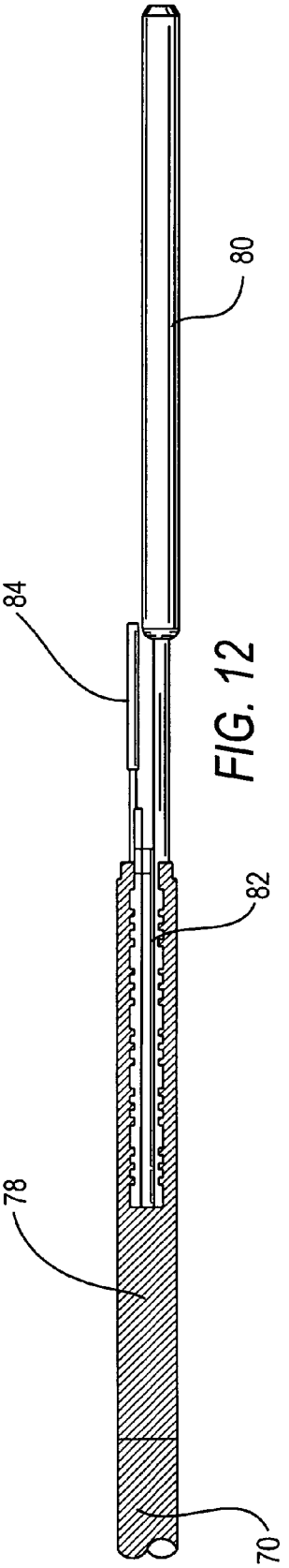
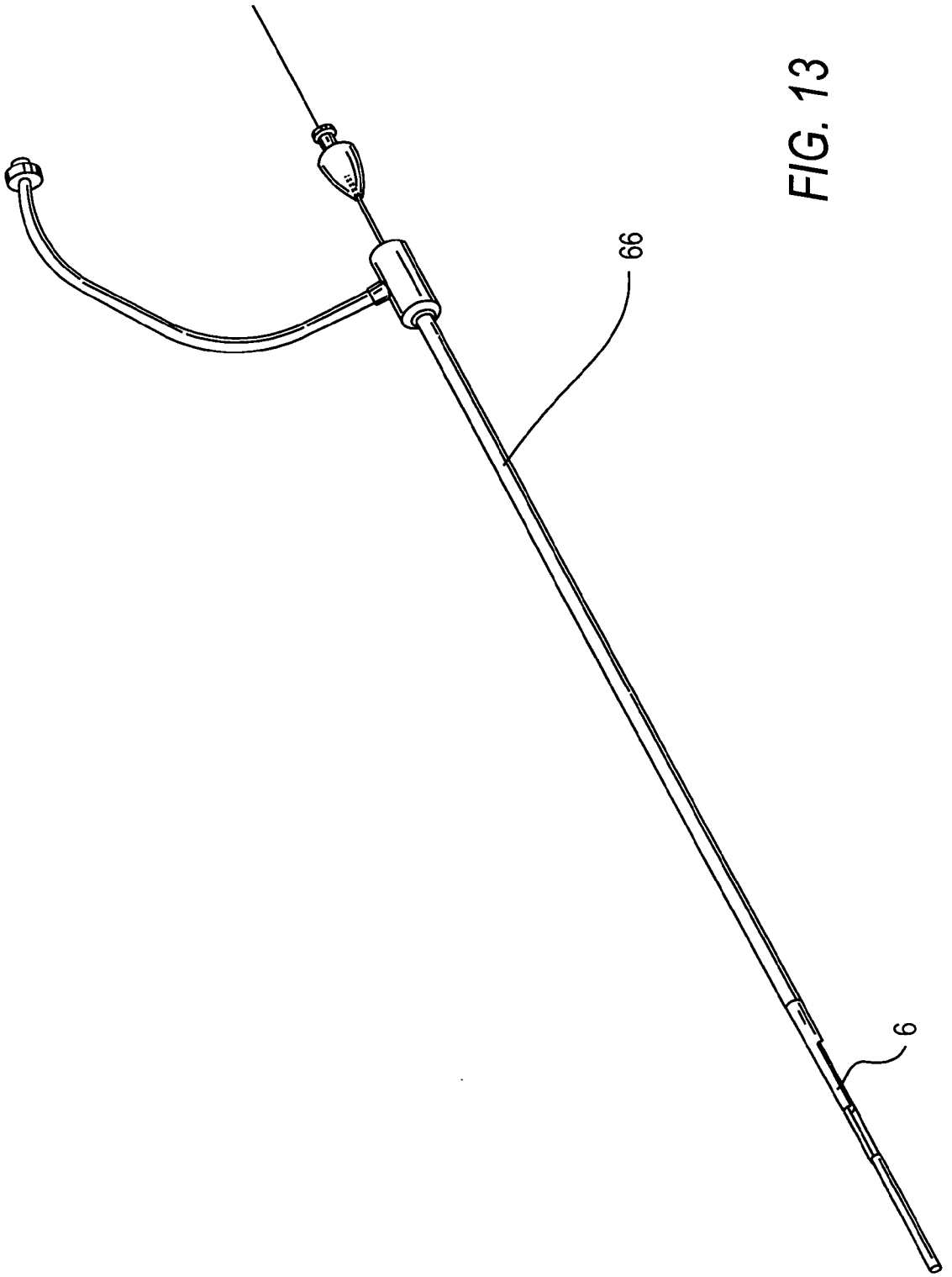


FIG. 12



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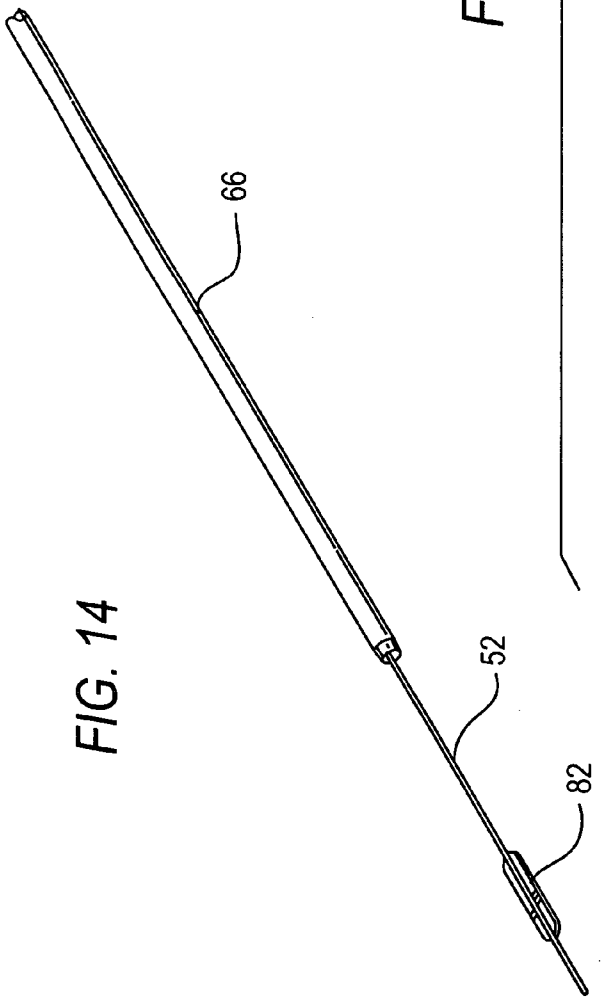


FIG. 14

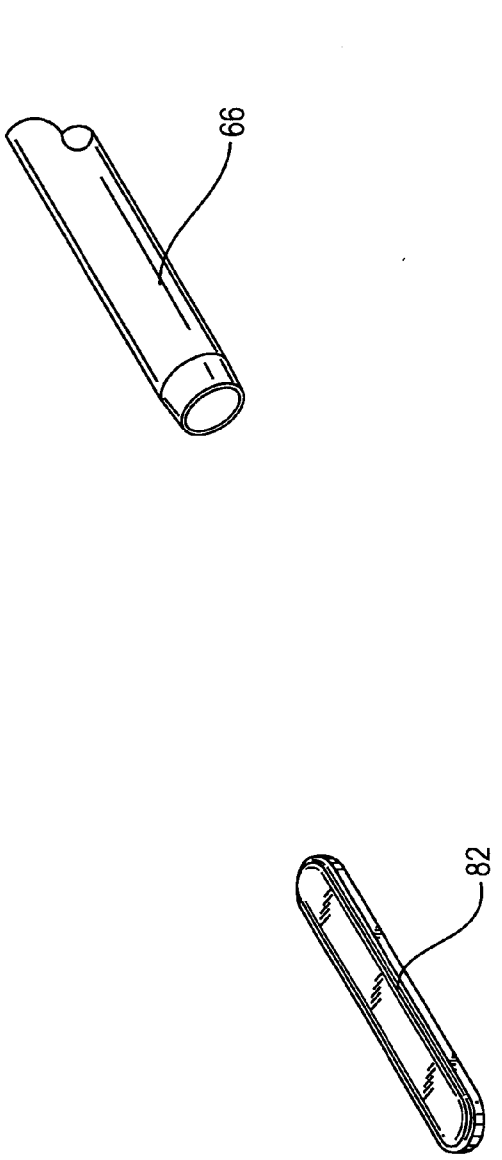


FIG. 15

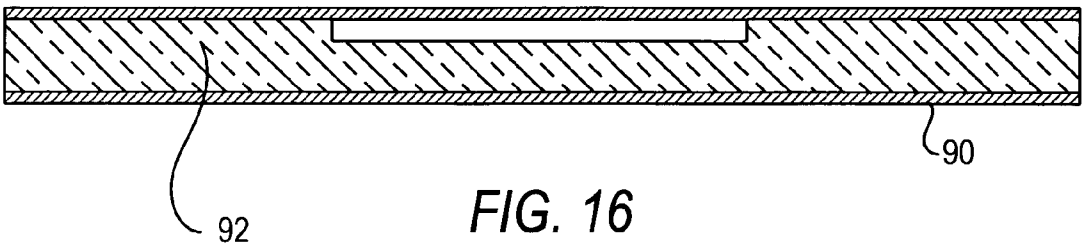


FIG. 16

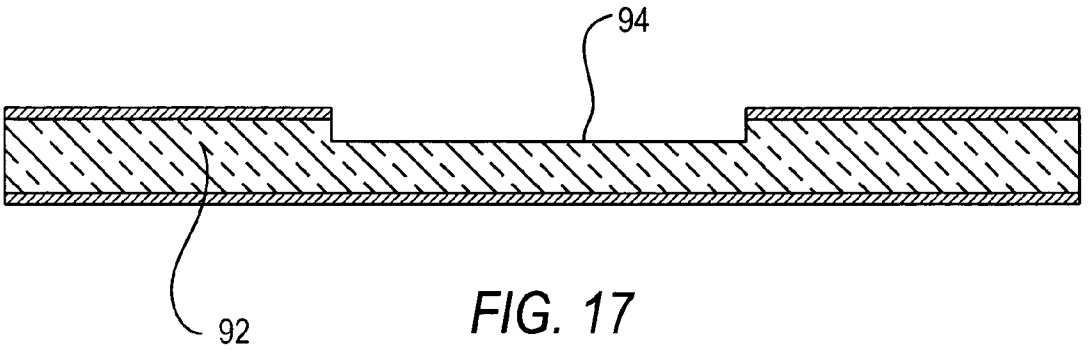


FIG. 17

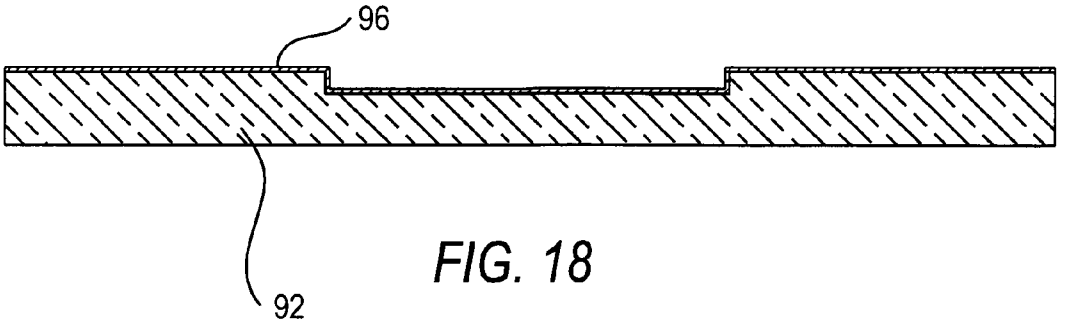


FIG. 18

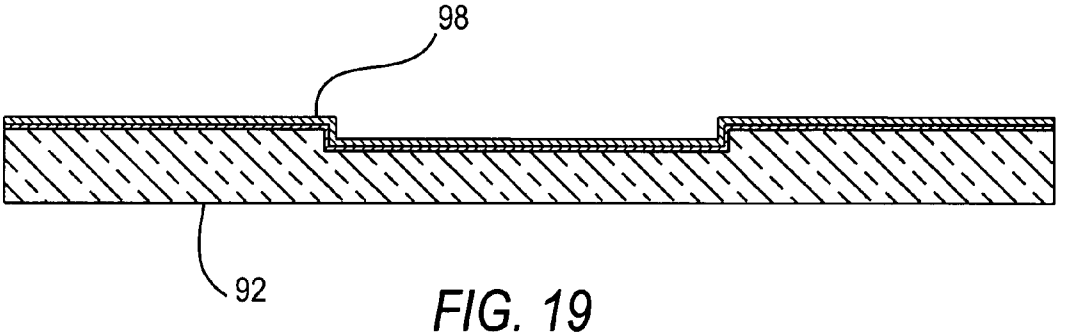


FIG. 19

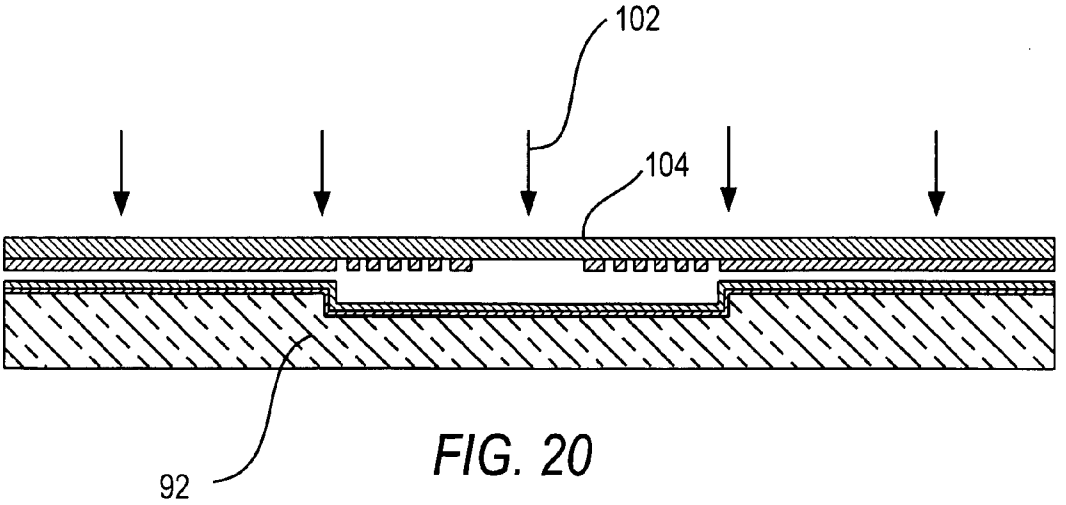


FIG. 20

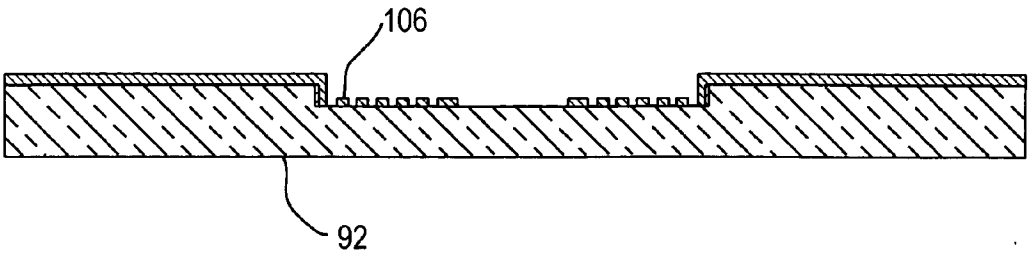
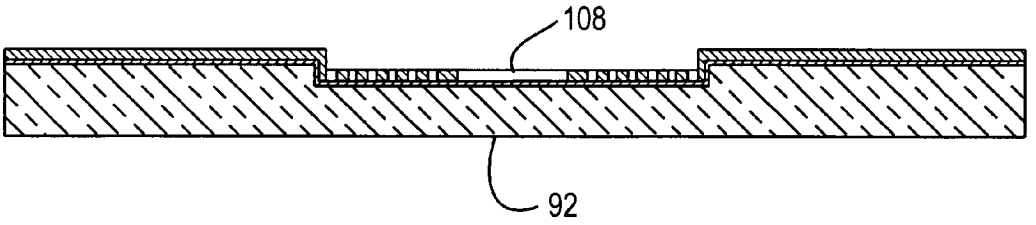


FIG. 21



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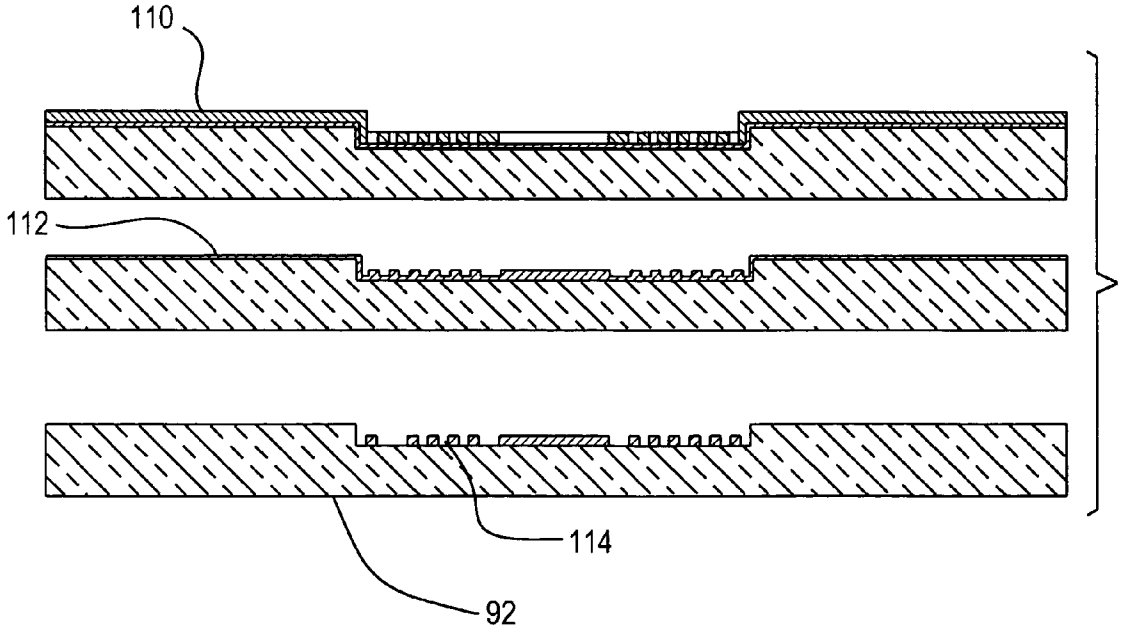

FIG. 23

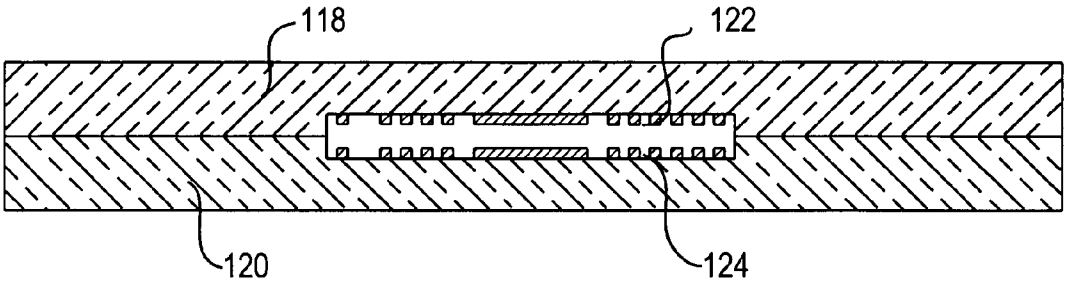

FIG. 24

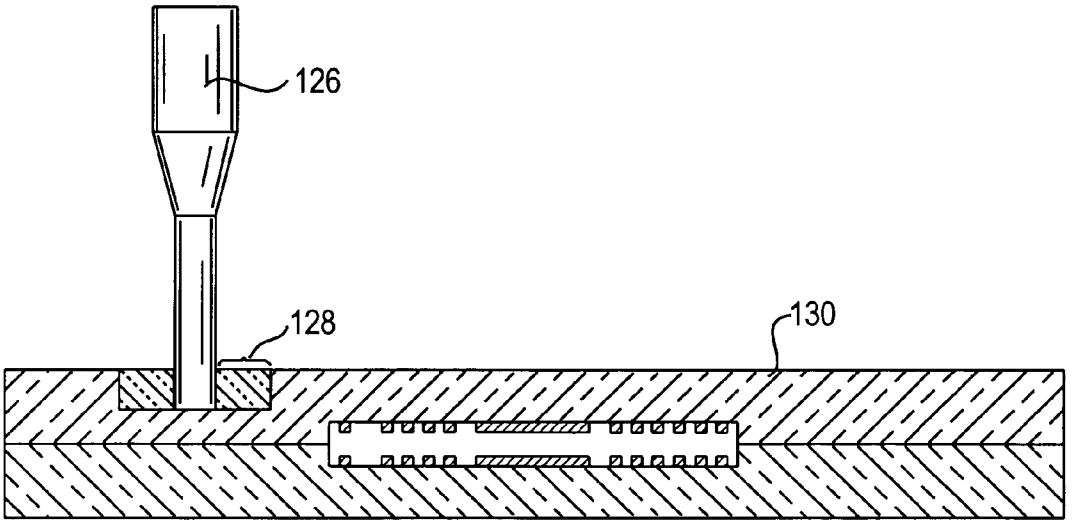

FIG. 25

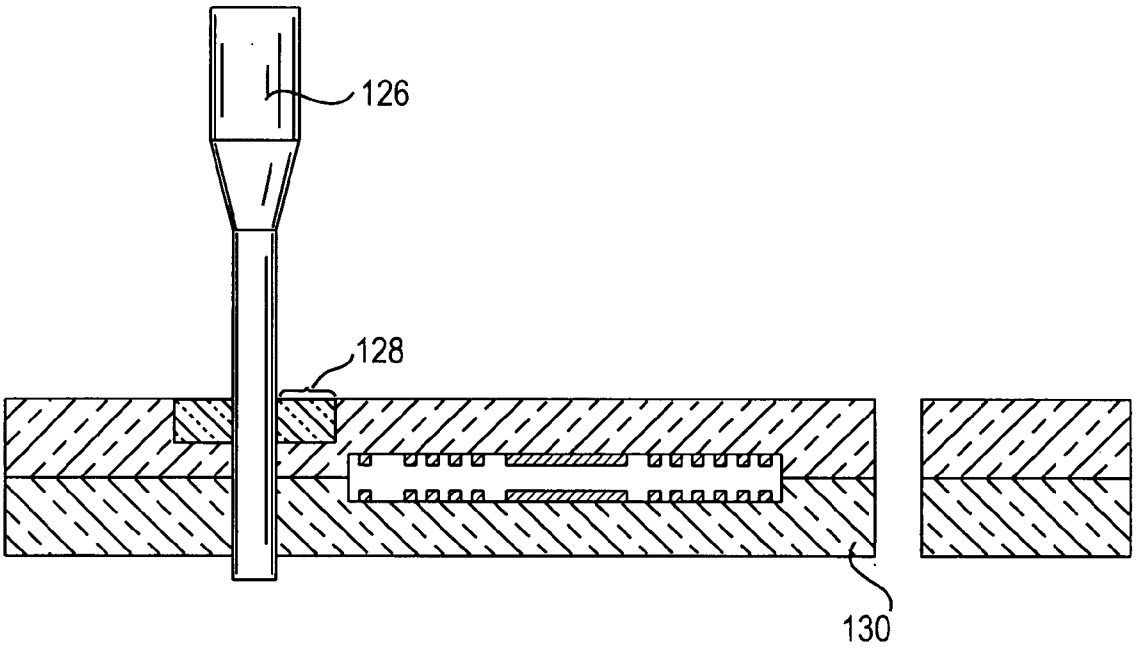

FIG. 26

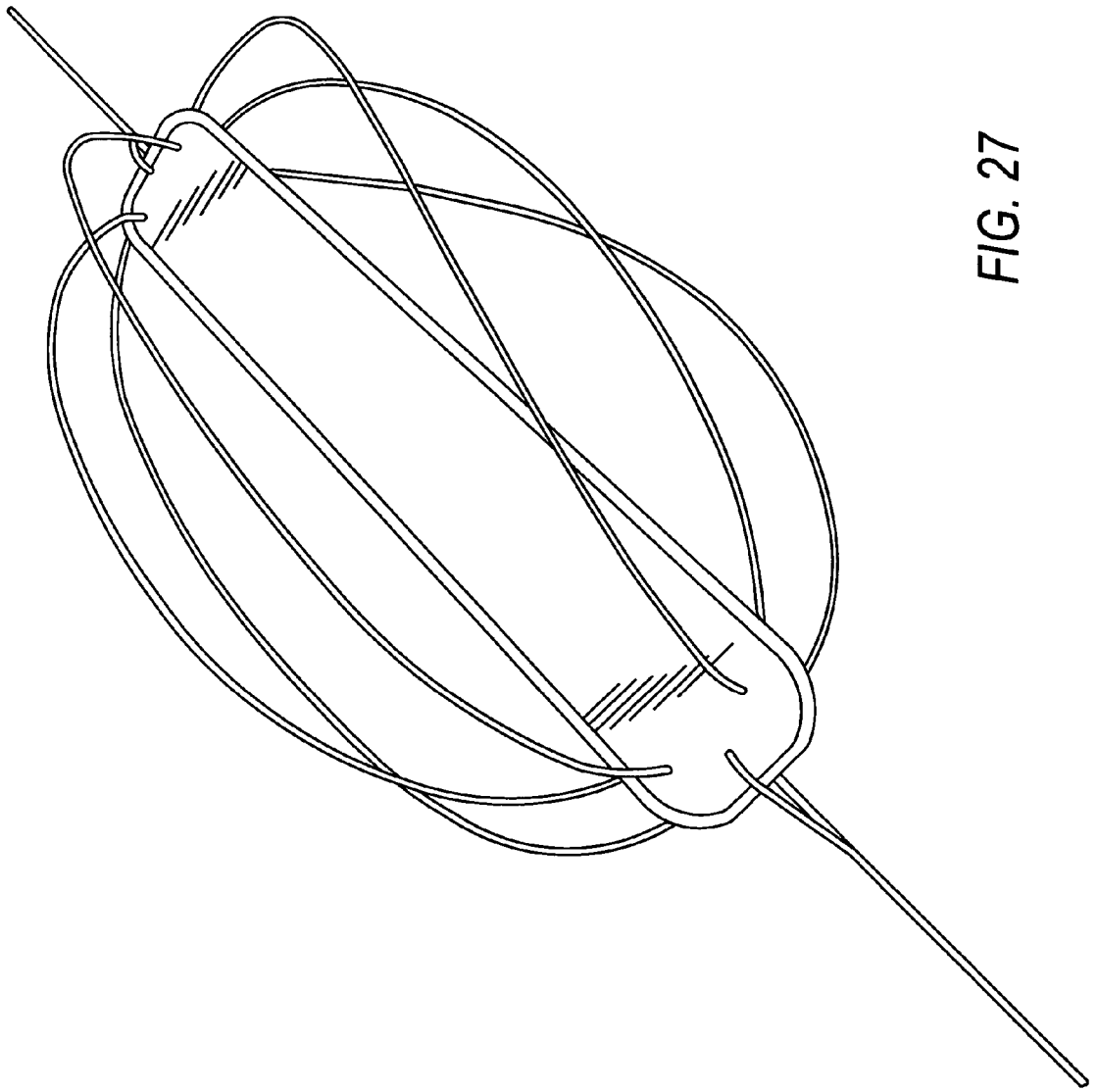

FIG. 27

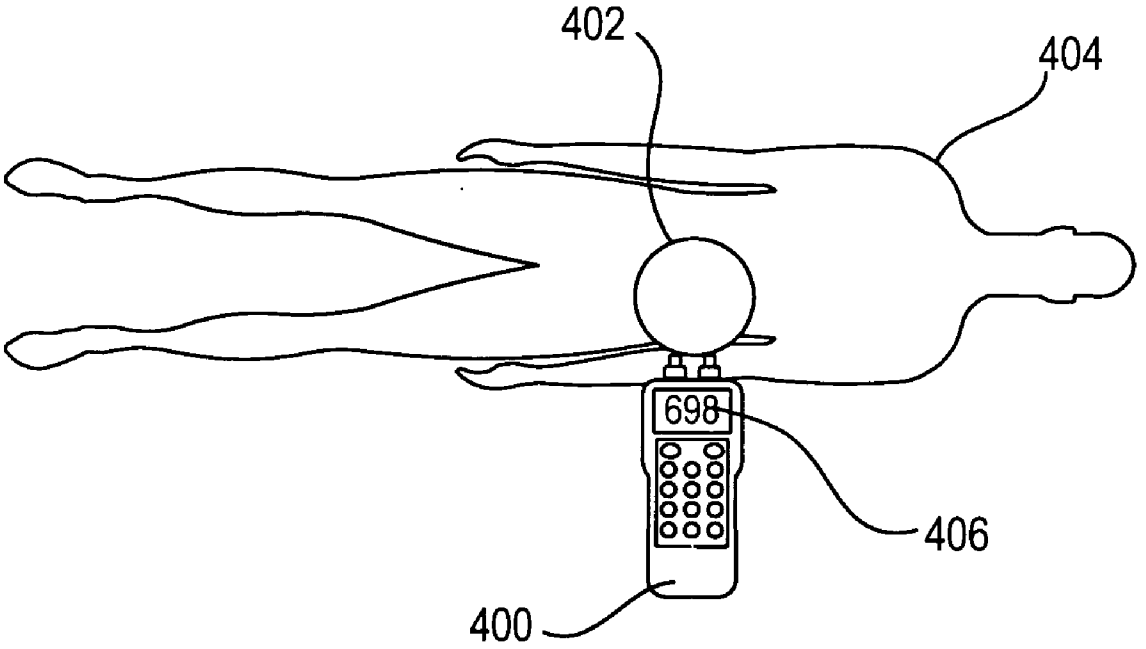

FIG. 28

IMPLANTABLE WIRELESS SENSOR

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is based upon co-pending, commonly assigned U.S. provisional patent application Ser. No. 60/503,745, filed Sep. 16, 2003, incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The application is directed to an implantable wireless sensor. More particularly, this invention is directed to a wireless, unpowered, micromechanical sensor that can be delivered using endovascular techniques, to measure a corporeal parameter such as pressure or temperature.

BACKGROUND OF THE INVENTION

[0003] Abdominal aortic aneurysms represent a dilatation and weakening of the abdominal aorta which can lead to aortic rupture and sudden death. Previously, the medical treatment of abdominal aortic aneurysms required complicated surgery with an associated high risk of injury to the patient. More recently, endografts (combining stents and grafts into a single device) have been developed that can be inserted through small incisions in the groin. Once in place, these endografts seal off the weakened section of the aorta. The aneurysms can then heal, eliminating the risk of sudden rupture. This less invasive form of treatment for abdominal aortic aneurysms has rapidly become the standard of care for this disease. An example of an endograft device is disclosed in Kornberg, U.S. Pat. No. 4,617,932.

[0004] A significant problem with endografts is that, due to inadequate sealing of the graft with the aorta, leaks can develop that allow blood to continue to fill the aneurysmal sac. Left undiscovered, the sac will continue to expand and potentially rupture. To address this situation, patients who have received endograft treatment for their abdominal aortic aneurysms are subjected to complex procedures that rely on injection of contrast agents to visualize the interior of the aneurysm sac. These procedures are expensive, not sensitive, and painful. In addition, they subject the patient to additional risk of injury. See, for example, Baum R A et al., "Aneurysm sac pressure measurements after endovascular repair of abdominal aortic aneurysms", *The Journal of Vascular Surgery*, January 2001, and Schurink G W et al., "Endoleakage after stent-graft treatment of abdominal aneurysm: implications on pressure and imaging—an in vitro study", *The Journal of Vascular Surgery*, August 1998. These articles provide further confirmation of the problem of endograft leakage and the value of intra-sac pressure measurements for monitoring of this condition.

[0005] Thus, there is a need for a method of monitor the pressure within an aneurysm sac that has undergone repair by implantation of an endograft to be able to identify the potential presence of endoleaks. Furthermore, this method should be accurate, reliable, safe, simple to use, inexpensive to manufacture, convenient to implant and comfortable to the patient.

[0006] An ideal method of accomplishing all of the above objectives would be to place a device capable of measuring pressure within the aneurysm sac at the time of endograft insertion. By utilizing an external device to display the pressure being measured by the sensor, the physician will obtain an immediate assessment of the success of the endograft at time of the procedure, and outpatient follow-up visits will allow simple monitoring of the success of the endograft implantation.

[0007] An example of an implantable pressure sensor designed to monitor pressure increases within an aneurysmal sac is shown in Van Bockel, U.S. Pat. No. 6,159,156. While some of the above objectives are accomplished, this device has multiple problems that would make its use impractical. For example, the sensor system disclosed in the Van Bockel patent relies on a mechanical sensing element that cannot be practically manufactured in dimensions that would allow for endovascular introduction. In addition, this type of pressure sensor would be subject to many problems in use that would limit its accuracy, stability and reliability. One example would be the interconnection of transponder and sensor as taught by Van Bockel, such interconnection being exposed to body fluids which could disrupt its function. This would impact the device's ability to maintain accurate pressure reading over long periods of time. A fundamental problem with sensors is their tendency to drift over time. A sensor described in the Van Bockel patent would be subject to drift as a result of its failure to seal the pressure sensing circuit from the external environment. Also, by failing to take advantage of specific approaches to electronic component fabrication, allowing for extensive miniaturization, the Van Bockel device requires a complex system for acquiring data from the sensor necessary for the physician to make an accurate determination of intra-aneurysmal pressure.

OBJECTS OF THE INVENTION

[0008] It is an object of this invention to provide an implantable wireless sensor.

[0009] It is also an object of this invention to provide a wireless, unpowered, micromechanical sensor that can be delivered endovascularly.

[0010] It is a further object of this invention to provide an implantable, wireless, unpowered sensor that can be delivered endovascularly to measure pressure and/or temperature.

[0011] It is a yet further object of this invention to provide a method of preparing a micromechanical implantable sensor.

[0012] It is a yet further object of this invention to provide a micromechanical sensor with a hermetically sealed, unbreached pressure reference for enhanced stability.

[0013] These and other objects of the invention will become more apparent from the discussion below.

SUMMARY OF THE INVENTION

[0014] The present invention comprises a device that can be implanted into the human body using non-surgical techniques to measure a corporeal parameter such as pressure, temperature, or both. Specific target locations could include the interior of an abdominal aneurysm or a chamber of the heart. This sensor is fabricated using MicroElectroMechanical Systems (MEMS) technology, which allows the creation of a device that is small, accurate, precise, durable, robust, biocompatible, radiopaque and insensitive to changes in

body chemistry, biology or external pressure. This device will not require the use of wires to relay pressure information externally nor need an internal power supply to perform its function.

[0015] The MEMS approach to sensor design lends itself to the fabrication of small sensors that can be formed using biocompatible materials as substrate materials. The pressure sensor described above can be introduced into the sac of an abdominal aneurysm at the time an endograft is deployed within the aorta by using standard endovascular catheter techniques. Appropriately biocompatible coatings may be applied to the surface of the sensor to prevent adhesion of biological substances or coagulated blood to the sensor that could interfere with its proper function.

[0016] In one embodiment of the invention an implantable wireless sensor comprises two substrates, at least one of which has a recess. The sensor comprises a self-contained resonant circuit comprising a capacitor and an inductor, where the circuit is variable in response to a physical property, or changes in a physical property, of a patient. The substrates are sealed together to form a hermetically scaled chamber, preferably one that is pressure sensitive.

[0017] In another embodiment of the invention one surface of each substrate comprises an inductor coil such as a wire spiral arranged in planar fashion. When the substrates are sealed together, the wire spirals are in planes parallel to each other.

[0018] In another embodiment of the invention each inductor coil is connected by a wire to a capacitor plate arranged in the middle of the respective coil. The capacitor plates are substantially planar to the respective inductor coils and are substantially arranged parallel to each other.

[0019] In another embodiment of the invention the sensor may comprise a metallic basket arranged exterior to the substrates.

[0020] Delivery of the device of the invention to an aneurysm may be accomplished as follows: Using the standard Seldinger technique, the physician gains access to the patient's femoral artery and places a vessel introducer with a hemostatic valve. Under direct fluoroscopic visualization, a flexible guidewire is inserted through the introducer catheter and maneuvered such that its tip is stationed within the sac of the aortic aneurysm. A standard vessel introducer is inserted over the guidewire and through the introducer and advanced distally until its tip is within the aneurysmal sac. The inner dilator of the vessel introducer is removed and a sensor delivery vehicle is inserted the inner lumen of introducer. The delivery vehicle consists of a polymer support tube with two channels that run through its length, a metal or rigid sensor support capsule in which the sensor is placed and atraumatic tip.

[0021] The sensor is attached to a tethering system consisting of a hollow tube with small diameter flexible wire disposed within. Near the terminal end of the hollow tube, a small break in the tube's surface is made. The flexible tether wire emerges out of this break, is threaded through a small hole in the rear section of the sensor, placed over the sensor, inserted through an identical hole in the forward segment of the sensor and re-inserted back into the hollow tube in a similar break in the tube's surface. In this configuration, the sensor remains secured to the tether wire after the delivery vehicle is removed from the patient. Following the insertion and deployment of the stent-graft, the sensor is detached from the tether wire by simply retracting the wire from the hollow tube. Once the wire has been pulled through the two holes in the sensor, the sensor is released into the aneurysm sac and the wire and hollow tube are removed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] **FIG. 1** is an oblique perspective view of an embodiment of the invention;

[0023] **FIG. 2** is a top, partly cross-sectional view of the embodiment of the invention shown in **FIG. 1**;

[0024] **FIG. 3** is a top, partly cross-sectional view of another embodiment of the invention;

[0025] **FIG. 4** is an oblique, cross-sectional view of the embodiment of the invention shown in **FIG. 2**;

[0026] **FIG. 5** is an oblique, cross-sectional view of the embodiment of the invention shown in **FIG. 3**;

[0027] **FIG. 6** is a exposed cross-sectional view of the embodiment of the invention shown in **FIG. 5**;

[0028] **FIG. 7** shows part of the sensor tethering system;

[0029] **FIG. 8** shows the further details of the tethering system;

[0030] FIGS. **9** to **12** show additional details of the tethering system;

[0031] FIGS. **13** to **15** show details of the delivery system;

[0032] FIGS. **16** to **26** show details of the manufacturing process used to fabricate the invention;

[0033] **FIG. 27** represents an additional embodiment of the invention; and

[0034] **FIG. 28** is a schematic of a control system.

DETAILED DESCRIPTION OF THE INVENTION

[0035] The invention can perhaps be better understood by referring to the drawings. **FIG. 1** is an oblique, perspective view of a sensor **2**, an embodiment of the invention. Sensor **2** preferably has an outer coating of biocompatible silicone.

[0036] **FIG. 2** is a top, partial cross-section of a schematic representation of sensor **2** where a wire spiral inductor coil **4** is positioned in planar fashion in a substrate **6**. Optionally sensor **2** may have recesses **8**, each with a hole **10**, to receive a tether wire (not shown here) for delivery of the device into a human patient, as described below.

[0037] In the embodiment of the invention shown in **FIG. 3**, a wire **12** connects coil **4** to a capacitor plate **14** positioned within coil **4**.

[0038] **FIG. 4** is a slightly oblique cross-section across its width of the embodiment of the invention shown in **FIG. 2**, where it can be seen that sensor **2** is comprised of a lower substrate **20** and an upper substrate **22**. Lower substrate **20** and upper substrate **22** are constructed from a suitable material, such as glass, fused silica, sapphire, quartz, or silicon. Fused silica is the preferred material of construction. Lower substrate **20** has on its upper surface **24** an induction coil **26**, and upper substrate **22** has a recess **28** with a surface

30 having an induction coil **32** thereon. The top surface of upper substrate **22** forms a membrane **34** capable of mechanically responding to changes in a patient's physical property, such as pressure. The end **36** of sensor **2** has a notch or recess **38**.

[**0039**] In similar fashion, **FIG. 5** is a slightly oblique cross-section across its width of the embodiment of the invention shown in **FIG. 3**. The primary difference between **FIGS. 4 and 5** is the presence of upper capacitor plate **42** and lower capacitor plate **44** on surfaces **24** and **30**, respectively. In the embodiment of **FIG. 4**, the spiral coil **4** itself acts as the capacitive element of the LC circuit that describes the operation of the sensor.

[**0040**] **FIG. 6** is a variation of **FIG. 5** where the outline of upper substrate **22** is shown but the details of lower substrate **20** can be seen more clearly, including individual coils of inductor coil **26**. A wire **46** connects lower capacitor plate **44** to induction coil **26**.

[**0041**] The size of the sensors of the invention will vary according to factors such as the intended application, the delivery system, etc. The oval sensors are intended to be from about 0.5 in. to about 1 in. in length and from about 0.1 in. to about 0.5 in. in width, with a thickness of from about 0.05 in. to about 0.30 in.

[**0042**] As shown in **FIGS. 4 and 5**, upper substrate **22** can be significantly thinner than lower substrate **20**. By way of example, upper substrate **22** may be from about 100 to about 300 microns thick, whereas lower substrate **20** may be from about 500 to about 1500 microns thick. In an alternate embodiment of the invention, both substrates may be of the same thickness ranging from about 100 to about 1000 microns.

[**0043**] In the embodiment of the invention shown in **FIG. 7**, a sensor **50** is attached to a hollow tube **52** that has a flexible tip **54**.

[**0044**] **FIG. 8** shows the sensor **50** and specific features of the tethering system, namely proximal holes **56** and distal holes **58** disposed in a hollow tube **52**.

[**0045**] **FIG. 9** shows a tether wire **60** that is attached to sensor **50** at sensor holes **62** and hollow tube holes **56** and **58**, and a tether wire **60** is positioned slidably within a hollow tube **52**.

[**0046**] A better appreciation of certain aspects of the invention, especially of a delivery system, can be obtained from **FIG. 10** which shows a vessel introducer **66** and the delivery system **68**.

[**0047**] Further details of the delivery system are shown in **FIG. 11**. A double lumen tube **70** has one channel that accepts a guidewire **72** and a second channel that accepts the sensor tether wire. The guidewire **72** can be advanced through hub **74**. A rigid delivery capsule **78** is disposed at the far end of the delivery catheter and flexible tip **80** is connected to the catheter via a hollow tube **81** extending through the delivery capsule **78**. A sensor **82** is positioned inside a slot in the delivery capsule **78** proximal to flexible tip **80**.

[**0048**] **FIG. 12** shows a lateral, cross-sectional view of this arrangement where the sensor **82** is inside the slot of delivery capsule **78** and the flexible tip **84** of the tether wire is disposed between the end of delivery capsule **78** and flexible tip **80**.

[**0049**] **FIG. 13** shows delivery catheter **68** loaded into the previously placed vessel introducer **66** prior to introduction of the sensor into the body.

[**0050**] **FIG. 14** shows that the sensor **82** on tether tube **52** has been advanced out of delivery capsule **78** and the delivery catheter has been removed.

[**0051**] In **FIG. 15**, the tether wire has been retracted into the hollow tether tube, releasing the sensor. The tether wire, tether tube and vessel introducer **66** are then all removed.

[**0052**] The pressure sensor of the invention can be manufactured using Micro-machining techniques that were developed for the integrated circuit industry. An example of this type of sensor features an inductive-capacitive (LC) resonant circuit with a variable capacitor, as is described in Allen et al., U.S. Pat. Nos. 6,111,520 and 6,278,379, all of which are incorporated herein by reference. The sensor contains two types of passive electrical components, namely, an inductor and a capacitor. The sensor is constructed so that the fluid pressure at the sensor's surface changes the distance between the capacitor's substantially parallel plates and causes a variation of the sensor's capacitance.

[**0053**] In a preferred embodiment the sensor of the invention is constructed through a series of steps that use standard MEMS manufacturing techniques.

[**0054**] **FIG. 16** shows the first step of this process in which a thin layer of metal (Protective mask) **90** is deposited onto the top and bottom surface of a fused silica wafer **92** (alternative materials would be glass, quartz, silicon or ceramic). Wafer diameters can range from about 3 to about 6 in. Wafer thickness can range from about 100 to about 1500 microns. A pattern mask is then created on one side of the wafer to define the location of cavities that need to be etched into the surface.

[**0055**] **FIG. 17** shows trenches or cavities **94** are etched into one surface of the wafer **92** to depths ranging from about 20 to about 200 microns. This etching is accomplished using any combination of standard wet and dry etching techniques (acid etch, plasma etch, reactive ion etching) that are well known in the MEMS industry. The protective metal mask is removed using standard metal etching techniques.

[**0056**] In **FIG. 18**, a thin metal seed layer **96** (typically chromium) is deposited on the etched side of the wafer using standard metal deposition techniques such as sputtering, plating or metal evaporation.

[**0057**] In **FIG. 19 a** layer of photo-resistive material **98** is applied to the etched surface of the wafer using standard spin coating procedures.

[**0058**] **FIG. 20** shows that a mask aligner and UV light **102** is used in a photolithographic processes to transfer a pattern from a mask **104** to the photoresist coating on the wafer.

[**0059**] In **FIG. 21**, the non-masked portions of the Photoresist are removed chemically creating a mold **106** of the desired coil pattern.

[0060] **FIG. 22** shows copper **108** electroplated into the mold to the desired height, typically from about 5 to about 35 microns.

[0061] In **FIG. 23**, the Photoresist **110** and seed layer **112** are etched away leaving the plated copper coils **114**.

[0062] This process is then repeated with a second wafer.

[0063] In **FIG. 24**, the two processed wafers **118** and **120** are aligned such that the cavities **122** and **124** with plated coils are precisely orientated in over one another and temporarily bonded to each other.

[0064] **FIGS. 25 and 26** show that by using a CO_2 laser **126** (or other appropriate laser type), the individual sensors **130** are cut from the glass wafer. The laser cutting process results in a permanent, hermetic seal between the two glass wafers. The laser energy is confined to a precise heat effect zone **128** in which the hermetic seal is created.

[0065] **FIG. 27** represents an embodiment of the invention wherein a sensor **132** attached to a delivery catheter **134** has a stabilizer or basket **136**. The stabilizer can be any appropriate device or structure that can be fixedly attached to a sensor of the invention to assist the sensor in maintaining position, location, and/or orientation after the sensor is delivered to an intended site. The stabilizer can comprise any appropriate physiologically acceptable rigid or slightly flexible material, such as stainless steel, nitinol, or a radiopaque metal or alloy.

[0066] This sensor design provides many important benefits to sensor performance. The hermetic seal created during the laser cutting process, coupled with the design feature that the conductor lines of the sensor are sealed within the hermetic cavity, allows the sensor to remain stable and drift free during long time exposures to body fluids. In the past, this has been a significant issue to the development of sensors designed for use in the human body. The manufacturing methodology described above allows many variations of sensor geometry and electrical properties. By varying the width of the coils, the number of turns and the gap between the upper and lower coils the resonant frequency that the device operates at and the pressure sensitivity (i.e., the change in frequency as a result of membrane deflection) can be optimized for different applications. In general, the design allows for a very small gap between the coils (typically between about 3 and about 35 microns) that in turn provides a high degree of sensitivity while requiring only a minute movement of the coils to sense pressure changes. This is important for long term durability, where large membrane deflection could result in mechanical fatigue of the pressure sensing element.

[0067] The thickness of the sensor used can also be varied to alter mechanical properties. Thicker wafers are more durable for manufacturing. Thinner sensors allow for creating of thin pressure sensitive membranes for added sensitivity. In order to optimize both properties the sensors may be manufactured using wafers of different thicknesses. For example, one side of the sensor may be constructed from a sensor of approximate thickness of 200 microns. This wafer is manufactured using the steps outlined above. Following etching, the thickness of the pressure sensitive membrane (i.e., the bottom of the etched trench) is in the range of from about 85 to about 120 microns. The matching wafer is from about 500 to about 1000 microns thick. In this wafer, the trench etching step is eliminated and the coils are plated directly onto the flat surface of the wafer extending above the wafer surface a height of from about 20 to about 40 microns. When aligned and bonded, the appropriate gap between the top and bottom coils is created to allow operation preferably in a frequency range of from 30 to 45 MHz and have sensitivity preferably in the range of from 5 to 15 kHz per millimeter of mercury. Due to the presence of the from about 500 to about 1000 micron thick wafer, this sensor will have added durability for endovascular delivery and for use within the human body.

[0068] The sensor exhibits the electrical characteristics associated with a standard LC circuit. An LC circuit can be described as a closed loop with two major elements, a capacitor and an inductor. If a current is induced in the LC loop, the energy in the circuit is shared back and forth between the inductor and capacitor. The result is an energy oscillation that will vary at a specific frequency. This is termed the resonant frequency of the circuit and it can be easily calculated as its value is dependent on the circuit's inductance and capacitance. Therefore, a change in capacitance will cause the frequency to shift higher or lower depending upon the change in the value of capacitance.

[0069] As noted above, the capacitor in the assembled pressure sensor consists of the two circular conductive segments separated by an air gap. If a pressure force is exerted on these segments it will act to move the two conductive segments closer together. This will have the effect of reducing the air gap between them which will consequently change the capacitance of the circuit. The result will be a shift in the circuit's resonant frequency that will be in direct proportion to the force applied to the sensor's surface.

[0070] Because of the presence of the inductor, it is possible to electromagnetically couple to the sensor and induce a current in the circuit. This allows for wireless communication with the sensor and the ability to operate it without the need for an internal source of energy such as a battery. Thus, if the sensor is located within the sac of an aortic aneurysm, it will be possible to determine the pressure within the sac in a simple, non-invasive procedure by remotely interrogating the sensor, recording the resonant frequency and converting this value to a pressure measurement. The readout device generates electromagnetic energy that penetrates through the body's tissues to the sensor's implanted location. The sensor's electrical components absorb a fraction of the electromagnetic energy that is generated by the readout device via inductive coupling. This coupling induces a current in the sensor's circuit that oscillates at the same frequency as the applied electromagnetic energy. Due to the nature of the sensor's electromechanical system there exists a frequency of alternating current at which the absorption of energy from the readout device is at a maximum. This frequency is a function of the capacitance of the device. Therefore, if the sensor's capacitance changes, so will the optimal frequency at which it absorbs energy from the readout device. Since the sensor's capacitance is mechanically linked to the fluid pressure at the sensor's surface, a measurement of this frequency by the readout device gives a relative measurement of the fluid pressure. If calibration of the device is performed, then an absolute measurement of pressure can be made. See, for example, the extensive discussion in the Allen et al. patent, again incor-

porated herein by reference, as well as Gershenfeld et al., U.S. Pat. No. 6,025,725, incorporated herein by reference. Alternative readout schemes, such as phase-correlation approaches to detect the resonant frequency of the sensor, may also be employed.

[0071] The pressure sensor is made of completely passive components having no active circuitry or power sources such as batteries. The pressure sensor is completely self-contained having no leads to connect to an external circuit or power source. Furthermore, these same manufacturing techniques can be used to add additional sensing capabilities, such as the ability to measure temperature by the addition of a resistor to the basic LC circuit or by utilizing changes in the back pressure of gas intentionally sealed within the hermetic pressure reference to change the diaphragm position and therefore the capacitance of the LC circuit.

[0072] It is within the scope of the invention that the frequency response to the sensor will be in the range of from about 1 to about 200 MHz, preferably from about 1 to about 100 MHz, and more preferably from about 2 to about 90 MHz, and even more preferably from about 30 to about 45 MHz, with a Q factor of from about 5 to about 150, optimally from about 5 to about 80, preferably from about 40 to about 100, more preferably from about 50 to about 90.

[0073] In a further embodiment of the invention there is no direct conductor-based electrical connection between the two sides of the LC circuit. Referring again to the sensor described in the Allen et al. patents, the device is constructed using multiple layers upon lie the necessary circuit elements. Disposed on the top and bottom layer are metal patterns constructed using micro-machining techniques which define a top and bottom conductor and a spiral inductor coil. To provide for an electrical contact between the top and bottom layers small vias or holes are cut through the middle layers. When the layers are assembled, a metal paste is forced into the small vias to create direct electrical connections or conduits. However, experimentation has shown that due to additional capacitance that is created between the top and bottom inductor coils, a vialess operational LC circuit can be created. This absence of via holes represents a significant improvement to the sensor in that it simplifies the manufacturing process and, more importantly, significantly increases the durability of the sensor making it more appropriate for use inside the human body.

[0074] Further, the invention is not limited to the implantation of a single sensor. Multiple pressure sensors may be introduced into the aneurysm space, each being positioned at different locations. In this situation, each sensor may be designed with a unique signature (obtained by changing the resonant frequency of the sensor), so that the pressure measurement derived from one sensor can be localized to its specific position within the aneurysm.

[0075] A significant design factor that relates to the performance of the sensor and the operation of the system is the Quality factor (Q) associated with the sensor. The value of Q is one of the key determinates as to how far from the sensor the external read-out electronics can be located while still maintaining effective communication. Q is defined as a measure of the energy stored by the circuit divided by the energy dissipated by the circuit. Thus, the lower the loss of energy, the higher the Q.

[0076] Additional increases in Q can be achieved by removing the central capacitive plate and using capacitive coupling between the copper coils to act as the capacitor element.

[0077] In operation, energy transmitted from the external read-out electronics will be stored in the LC circuit of the sensor. This stored energy will induce a current in the LC loop which will cause the energy to be shared back and forth between the inductor and capacitor. The result is an oscillation that will vary at the resonant frequency of the LC circuit. A portion of this ocscillating energy is then coupled back to the receiving antenna of the read-out electronics. In high Q sensors, most of the stored energy is available for transmission back to the electronics, which allows the distance between the sensor and the receiving antenna to be increased. Since the transmitted energy will decay exponentially as it travels away from the sensor, the lower the energy available to be transmitted, the faster it will decay below a signal strength that can be detected by the receiving antenna and the closer the sensor needs to be situated relative to the receiving electronics. In general then, the lower the Q, the greater the energy loss and the shorter the distance between sensor and receiving antenna required for sensor detection.

[0078] The Q of the sensor will be dependent on multiple factors such as the shape, size, diameter, number of turns, spacing between turns and cross-sectional area of the inductor component. In addition, Q will be greatly affected by the materials used to construct the sensors. Specifically, materials with low loss tangents will provide the sensor with higher Q factors.

[0079] The implantable sensor ascending to the invention is preferably constructed of various glasses or ceramics including but not limited to fused silica, quartz, pyrex and sintered zirconia, that provide the required biocompatibility, hermeticity and processing capabilities. Preferably the materials result in a high Q factor. These materials are considered dielectrics, that is, they are poor conductors of electricity, but are efficient supporters of electrostatic or electroquasiatatic fields. An important property of dielectric materials is their ability to support such fields while dissipating minimal energy. The lower the dielectric loss (the proportion of energy lost), the more effective the dielectric material in maintaining high Q. For a lossy dielectric material, the loss is described by the property termed "loss tangent." A large loss tangent reflects a high degree of dielectric loss.

[0080] With regard to operation within the human body, there is a second important issue related to Q, namely, that blood and body fluids are conductive mediums and are thus particularly lossy. The consequence of this fact is that when a sensor is immersed in a conductive fluid, energy from the sensor will dissipate, substantially lowering the Q and reducing the sensor-to-electronics distance. For example, the sensors described above were immersed in saline (0.9% salt solution), and the measured Q decreased to approximately 10. It has been found that such loss can be minimized by further separation of the sensor from the conductive liquid. This can be accomplished, for example, by encapsulating the sensor in a suitable low-loss-tangent dielectric material. However, potential encapsulation material must have the flexibility and biocompatibility characteristics of the sensor material and also be sufficiently compliant to allow trans-

mission of fluid pressure to the pressure sensitive diaphragm. A preferred material for this application is polydimethylsiloxane (silicone).

[0081] As an example, a thin (i.e., 200 micron) coating of silicone was applied to the sensor detailed above. This coating provided sufficient insulation to maintain the Q at **50** in a conductive medium. Equally important, despite the presence of the silicone, adequate sensitivity to pressure changes was maintained and the sensor retained sufficient flexibility to be folded for endovascular delivery. One additional benefit of the silicone encapsulation material is that it can be optionally loaded with a low percentage (i.e., 10-20%) of radio-opaque material (e.g., barium sulfate) to provide visibility when examined using fluoroscopic x-ray equipment. This added barium sulfate will not affect the mechanical and electrical properties of the silicone.

[0082] As described above, it is desirable to increase the Q factor of a sensor, and the Q factor can be increased by suitable selection of sensor materials or a coating, or both. Preferably both are used, because the resulting high Q factor of a sensor prepared in this fashion is especially suitable for the applications described.

[0083] When introduced into the sac of an abdominal aorta, the pressure sensor can provide pressure related data by use of an external measuring device. As disclosed in the Allen et al. patents, several different excitation systems can be used. The readout device generates electromagnetic energy that can penetrate through the body's tissues to the sensor's implanted location. The sensor's electrical components can absorb a fraction of the electromagnetic energy that is generated by the readout device via inductive coupling. This coupling will induce a current in the sensor's circuit that will oscillate at the same frequency as the applied electromagnetic energy. Due to the nature of the sensor's electromechanical system there will exist a frequency of alternating current at which the absorption of energy from the readout device is at a minimum. This frequency is a function of the capacitance of the device. Therefore, if the sensor's capacitance changes so will the frequency at which it minimally absorbs energy from the readout device. Since the sensor's capacitance is mechanically linked to the fluid pressure at the sensor's surface, a measurement of this frequency by the readout device can give a relative measurement of the fluid pressure. If calibration of the device is performed then an absolute measurement of pressure can be made.

[0084] The circuitry used to measure and display pressure is contained within a simple to operate, portable electronic unit **400**, as shown in **FIG. 28**. This unit **400** also contains the antenna needed to perform the electromagnetic coupling to the sensor. The antenna may be integrated into the housing for the electronics or it may be detachable from the unit so that it can be positioned on the surface of the body **402** in proximity to the implanted sensor and easily moved to optimize the coupling between antenna and sensor. The antenna itself may consist of a simple standard coil configuration or my incorporate ferrous elements to maximize the coupling efficiency. The electronic device would feature an LCD or LED display **404** designed to clearly display the recorded pressure in physiologically relevant units such as mm Hg. In an alternative embodiment, the display may be created by integrating a commercially available hand-held computing device such as a Palm® or micro-PC into the electronic circuitry and using this device's display unit as the visual interface between the equipment and its operator. A further advantage of this approach is that the hand-held computer could be detached from the read-out unit and linked to a standard desktop computer. The information from the device could thus be downloaded into any of several commercially available data acquisition software programs for more detailed analysis or for electronic transfer via hard media or the internet to a remote location.

[0085] Accordingly, the present invention provides for an impedance system and method of determining the resonant frequency and bandwidth of a resonant circuit within a particular sensor. The system includes a loop antenna, which is coupled to an impedance analyzer. The impedance analyzer applies a constant voltage signal to the loop antenna scanning the frequency across a predetermined spectrum. The current passing through the transmitting antenna experiences a peak at the resonant frequency of the sensor. The resonant frequency and bandwidth are thus determined from this peak in the current.

[0086] The method of determining the resonant frequency and bandwidth using an impedance approach may include the steps of transmitting an excitation signal using a transmitting antenna and electromagnetically coupling a sensor having a resonant circuit to the transmitting antenna thereby modifying the impedance of the transmitting antenna. Next, the step of measuring the change in impedance of the transmitting antenna is performed, and finally, the resonant frequency and bandwidth of the sensor circuit are determined.

[0087] In addition, the present invention provides for a transmit and receive system and method for determining the resonant frequency and bandwidth of a resonant circuit within a particular sensor. According to this method, an excitation signal of white noise or predetermined multiple frequencies is transmitted from a transmitting antenna, the sensor being electromagnetically coupled to the transmitting antenna. A current is induced in the resonant circuit of the sensor as it absorbs energy from the transmitted excitation signal, the current oscillating at the resonant frequency of the resonant circuit. A receiving antenna, also electromagnetically coupled to the transmitting antenna, receives the excitation signal minus the energy which was absorbed by the sensor. Thus, the power of the received signal experiences a dip or notch at the resonant frequency of the sensor. The resonant frequency and bandwidth are determined from this notch in the power.

[0088] The transmit and receive method of determining the resonant frequency and bandwidth of a sensor circuit includes the steps of transmitting a multiple frequency signal from transmitting antenna, and, electromagnetically coupling a resonant circuit on a sensor to the transmitting antenna thereby inducing a current in the sensor circuit. Next, the step of receiving a modified transmitted signal due to the induction of current in the sensor circuit is performed. Finally, the step of determining the resonant frequency and bandwidth from the received signal is executed.

[0089] Yet another system and method for determining the resonant frequency and bandwidth of a resonant circuit within a particular sensor includes a chirp interrogation system. This system provides for a transmitting antenna

which is electromagnetically coupled to the resonant circuit of the sensor. An excitation signal of white noise or predetermined multiple frequencies, or a time-gated single frequency is applied to the transmitting antenna for a predetermined period of time, thereby inducing a current in the resonant circuit of the sensor at the resonant frequency. The system then listens for a return signal which is coupled back from the sensor. The resonant frequency and bandwidth of the resonant circuit are determined from the return signal.

[0090] The chirp interrogation method for determining the resonant frequency and bandwidth of a resonant circuit within a particular sensor includes the steps of transmitting a multi-frequency signal pulse from a transmitting antenna, electromagnetically coupling a resonant circuit on a sensor to the transmitting antenna thereby inducing a current in the sensor circuit, listening for and receiving a return signal radiated from the sensor circuit, and determining the resonant frequency and bandwidth from the return signal.

[0091] The present invention also provides an analog system and method for determining the resonant frequency of a resonant circuit within a particular sensor. The analog system comprises a transmitting antenna coupled as part of a tank circuit which in turn is coupled to an oscillator. A signal is generated which oscillates at a frequency determined by the electrical characteristics of the tank circuit. The frequency of this signal is further modified by the electromagnetic coupling of the resonant circuit of a sensor. This signal is applied to a frequency discriminator which in turn provides a signal from which the resonant frequency of the sensor circuit is determined.

[0092] The analog method for determining the resonant frequency and bandwidth of a resonant circuit within a particular sensor includes the steps of generating a transmission signal using a tank circuit which includes a transmitting antenna, modifying the frequency of the transmission signal by electromagnetically coupling the resonant circuit of a sensor to the transmitting antenna, and converting the modified transmission signal into a standard signal for further application.

[0093] The invention further includes an alternative method of measuring pressure in which a non-linear element such as a diode or polyvinylidenedifloride piezo-electric polymer is added to the LC circuit. A diode with a low turn-on voltage such as a Schottky diode can be fabricated using micro-machining techniques. The presence of this non-linear element in various configurations within the LC circuit can be used to modulate the incoming signal from the receiving device and produce different harmonics of the original signal. The read-out circuitry can be tuned to receive the particular harmonic frequency that is produced and use this signal to reconstruct the fundamental frequency of the sensor. The advantage of this approach is two-fold; the incoming signal can be transmitted continuously and since the return signal will be at different signals, the return signal can also be received continuously.

[0094] The above methods lend themselves to the creation of small and simple to manufacture hand-held electronic devices that can be used without complication.

[0095] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention of the scope of the appended claims.

We claim:

1. A sensor for wirelessly determining a physical property, which sensor comprises:

a self-contained resonant circuit comprising a capacitor and an inductor, and

two substrates, at least one of which substrates has a recess therein,

wherein the circuit is variable in response to the physical property and wherein the substrates are hermetically sealed together.

2. The sensor of claim 1, wherein the hermetically sealed substrates form a pressure sensitive chamber.

3. The sensor of claim 1, wherein the substrates are comprised of glass, fused silica, sapphire, quartz, or silicone.

4. The sensor of claim 3, wherein the substrates are comprised of fused silica.

5. The sensor of claim 1, wherein the physical property is pressure.

6. The sensor of claim 1, wherein there are no conductive connections or via holes to provide a direct physical conduit or connection between an upper inductor coil and a lower inductor coil.

7. The sensor of claim 1, wherein each substrate has an inductor coil arranged therein in planar fashion.

8. The sensor of claim 7, wherein the inductor coil of one substrate is in a plane parallel to the plane of the inductor coil in the second substrate.

9. The sensor of claim 8, wherein the inductor coils are coextensive.

10. The sensor of claim 1, wherein the inductor coil of the substrate with a recess is positioned in the recess.

11. The sensor of claim 10, wherein each substrate has a recess and an inductor coil is positioned in each recess.

12. The sensor of claim 1, wherein the inductor comprises to inductor coils and each inductor coil is a wire spiral.

13. The sensor of claim 12, wherein each wire spiral is formed by electrodeposition.

14. The sensor of claim 1, wherein the sensor is from about 0.5 in. to about 1 in. in length and from about 0.1 in. to about 0.5 in. in width.

15. The sensor of claim 14, wherein the sensor has a thickness of from about 0.05 in. to about 0.30 in.

16. The sensor of claim 1, wherein a stabilizer is arranged around the sensor.

17. The sensor of claim 16, wherein the stabilizer stabilizes position, location, and/or orientation.

18. The sensor of claim 16, wherein the stabilizer is a metal basket arranged around the outer surface of the sensor.

19. The sensor of claim 1, wherein the physical property is measured in a patient.

20. A system for delivering a sensor, which comprises a sensor of claim 1 and a delivery guidewire or catheter.

21. The system of claim 21, wherein the sensor is removable from the guidewire or catheter.

22. The system of claim 21, wherein the sensor is removably attached to the guidewire or catheter.

23. The system of claim 21 which also comprises an instrument for measuring signals from the sensor.

24. A method for measuring a physical property which comprises the steps of inserting a sensor of claim 1 into a desired location and then measuring any signals generated by said sensor.

25. The method of claim 24, wherein a physical property in a patient is measured.

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